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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/147,052 | 04/05/1999 | SHUJI SAITOH | 981167 | 1182 |

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| EXAMINER | |
|---|---|
| HINES, JANA A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1645 | |

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/147,052 | SAITOH ET AL. | |
| | Examiner | Art Unit | |
| | Ja-Na Hines | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *20-41 and 43-46* is/are pending in the application.

4a) Of the above claim(s) *31,34-38,45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30, 32-33 and 39-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2004 has been entered.

### *Amendment Entry*

2. The amendment filed May 12, 2004 has been entered. Claims 20, 25-26, 29-30, 32-33, 41 and 43-44 have been amended. Applicants again assert that claims 45-46 should be examined, however as previously stated claims 45-46 are directed to an invention that is independent or distinct from the invention originally claimed. The inventions are distinct as claimed because they have different structures, different uses, different functions, effects and are capable of use without the other. Accordingly, claims 45-46 are withdrawn from consideration as being directed to a non-elected invention as stated in the previous office actions. See 37 CFR 1.142(b) and MPEP § 821.03.

Therefore only claims 20-30, 32-33 and 39-44 are under consideration in this office action.

### *Withdrawal of Rejections*

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 20-24, 29-30 and 41-42 under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200.); and

b) The new matter rejection of claims 25-26, 32-33, 40-44 are rejected under 35 U.S.C. 112, first paragraph.

### *Response to Arguments*

4. Applicant's arguments with respect to claims 20-30, 32-33 and 39-44 have been considered but are moot in view of the new ground(s) of rejection.

### New Grounds for Rejection

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 20-30, 32-33 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitoh et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) and further in view of Nazerian et al. (EP 520,753).

Saitoh et al., (WO 94/23019) teach novel polypeptides, DNA coding for those polypeptides, recombinant vector containing the DNA, recombinant virus prepared using the vector and various uses (title). Saitoh et al., teach polypeptides that exhibit the antigenicity of *Mycoplasma gallisepticum*, as a fused polypeptide comprising the polypeptide and connected to the N-terminus thereof, a signal membrane anchor of a type II outer-membrane polypeptide of a virus that infects birds, or a polypeptide capable of reacting with a mycoplasma-immune serum or a mycoplasma-infected serum and exhibiting a substantially pure antigenicity, respectively having amino acid sequences of about 32 kDa, about 40 kDa or about 70 kDa. Saitoh et al., teach the same antigenic protein applicants recited as amino acid sequence 64-456 of SEQ ID NO:2. The expression with a recombinant virus of a polypeptide modified to such an extent as to exhibit an antigenicity equivalent to that of any of the above polypeptides. Saitoh et al., teach the use of a recombinant virus as a live vaccine (Abstract). Saitoh et al., also teach that the fused polypeptide can be used as an anti-*Mycoplasma gallisepticum* (MG) infectious disease vaccine and can be used as a recombinant fowlpox virus (FPV) which has DNA that codes for the signal membrane anchor and can be found by analyzing the hydrophobic peptide region on the N-terminus side of the type II envelope protein in reference to the amino acid sequence. However, Saitoh et al., do not specifically recite a polypeptide derived from a Herpes outer membrane protein.

Yoshida et al., (Virology 1994, vol. 200) teach the glycoprotein B genes of Marek's Disease Virus Serotypes 2 and 3 and the identification and expression by

recombinant fowlpox virus. Marek's disease is a malignant T-cell lymphoma of chickens caused by Marek's disease virus (MDV), an avian herpes virus (page 484 para. 1). MDV has been classified as a gamma-herpes virus based upon its tropism, however other studies based upon its gene arrangement indicate that it is more closely related to alpha-herpes virus (page 484 para. 1). The MDV-1 homolog of the herpes simplex virus glycoproteinB (gB) has been cloned and sequenced (page 484 para .3). This gene (gB-1) encodes the B-antigen complex: gp100, gp60 and gp49 (page 484 para. 3). The gB of Herpes Simplex Virus (HSV) is the best characterized of the HSV glycoproteins and it has been shown to be essential for virus infectivity (page 484 para. 5). The gB can be one if the major target of the host immune response and in many herpes viruses, it has been reported that gB homologs are well conserved (page 484 para. 5). The recombinant fowlpox virus (FPV) has been used to express foreign genes and to evaluate their immunogenic potential (page 484 para. 6). Previous studies show an FPV recombinant expressing the gB-1 gene to elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV (page 484-485-para, 6-1). That data suggest that FPV recombinant is a good candidate for an MDV vaccine and that gB is an important target for the host immune response (page 485 para. 1). An analysis of the predicted amino acid sequences was determined along with a 5' hydrophobic signal sequence which three of the gBps contain (page 487 para. 9). It was predicted that the N- terminal hydrophobic region of the gB-1 could serve as a signal sequence (page 488 para .1). Saito et al., (WO 94/23019) and Yoshida et al., (Virology

1994 Vol. 200) have been discussed above and in previous office actions, however neither teach a signal polypeptide with amino acids 1-672 of SEQ ID NO:4.

Nazerian et al., teach Marek's disease as a highly contagious neoplastic disease of domestic chickens and is caused by a highly cell-associated oncogenic herpesvirus known as Marek disease virus (MDV) (page 2). Recombinant DNA technology has allowed the construction of recombinant vaccines that contain only those desired viral genes or gene products that induce immunity without exposing the animal to genes that may induce pathological disorders (page 2). Pox viruses, including avipox virus provide excellent models for such vaccines since these viruses have large DNA molecule with numerous nonessential regions that allow the insertion of several immunogenic genes into the same virus for the purpose of creating multivalent vaccines (page 2). MDV homologus of the Herpes simplex virus gene code for glycoproteins that were cloned (page 2). It was an object of the invention to provide effective and safe vaccines against MDV that expose and immunize chickens to the immunogenic products of the vaccine (page 2). Example 2 teaches cloning of the gene to produce recombinant viruses used for immunizing chickens (page 5-6). Thereby teaching a signal polypeptide encompassing an identical sequence to both 1-63 of SEQ ID NO:1 and 1-672 of SEQ ID NO:4 as recited by the instant claims. Thus Nazerian et al., teach a signal polypeptide that is secreted extracellularly. Moreover, Nazerian et al, teach the ability of the recombinant fusion polypeptides comprised within the virus and vaccine as having the ability to induce humoral immunity in chickens (page 7-8) See also Table 1.

Therefore it would have been prima facie obvious at the time of applicants' invention to incorporate well known sequences, useful in the same field of art, that creates the same immunity as taught by Nazerian et al. No more than routine skill would have been required to use the signal polypeptide derived Herpes outer membrane protein from Yoshida et al., (Virology 1994 Vol. 200) and the fusion protein comprising an outer membrane protein that infects birds and vaccine of Saito et al., (WO 94/23019) because the prior art teaches that signal polypeptides are useful in directing polypeptides. One of ordinary skill in the art would have clearly been motivated to use the fused polypeptide comprising a signal polypeptide and exchange the signal polypeptide with that of Nazerian et al., because of the many beneficial effects that the prior art teaches. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent polypeptide since only the expected results are taught. The use of alternative signal polypeptides would have been desirable to those of ordinary skill in the art based on the fact that gB-1 gene elicits neutralizing antibody; fully protects chickens against virulent strains of MDV and it is a good candidate for an MDV vaccine.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
August 16, 2004

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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